IN THE CLAIMS

In claims 2, 4-6, 10 and 13, first line, change "1" to –21–.

In claim 15, line 1, change "1" to –21–. In line 2, delete "Eudragit L", insert -- poly(methacrylic acid-co-methylmethacrylate), 1:1, 135,000 MW--

In claim 18, line 1, change "1" to –21–. In line 2, remove "Eudragit L", --insert poly(methacrylic acid-co-methyl methacrylate), 1:1, 135,000 MW--. In lines 3- 4 delete "Eudragit S", insert --poly(methacrylic acid-co-methylmethacrylate), 1:2, 135,000 MW--

In claim 19, line 1, change "1" to –21–. In line 2, delete "Eudragit S or Eudragit FS 30D", insert –poly(methacrylic acid-co-methylmethacrylate), 1:2, 135,000 MW or poly(methyl acrylate-co-methyl methacrylate-co-trimethacrylic acid), 7:3:1, 400,000 MW--

Cancel claim 1, substitute therefore new claim 21.

21. An oral solid formulation comprising an active ingredient in an amount sufficient to treat inflammatory bowel disease, portions of the active ingredient being combined with different polymers or mixtures of polymers, each polymer or mixture of polymers being soluble starting from a pH value different from each other polymer or mixture of polymers, for a multiphasic release of the portion of the active ingredient in combination therewith as each polymer or mixture of polymers is dissolved, each phase of release occurring at a different pH value corresponding to the pH values of the different polymers or mixture of polymers, ranging from a pH of 6 to 7.

In claim 3, line 3, delete "preferably 30 to 35%". In line 4, delete "preferably 30 to 35%". In line 5, delete "preferably 30 to 35%".

Add new claim 22:

22. Formulation according to claim 2, wherein release of the active ingredient in every phase occurs in the pH dependent ratios:

pH=6 ⇒ 30-35% of the active ingredient

pH=6.5	⇒	30-35%	of the active ingredient
pH=7	⇒	30-35%	of the active ingredient.

REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-20 were in this application, claim 1 has been canceled, claims 3, 15, 18 and 19 have been amended and new claims 21 and 22 have been added. New claim 21 replaces original claim 1 and all the claims dependent on claim 1 have been amended to depend from claim 21. In claim 3, the alternative narrow ranges have been canceled from claim 3 and have been presented in new claim 22 so as to overcome the rejection under 35 U.S.C. Section 112.

Claims 15, 18 and 19 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite for use of the trade name "Eudragit". These claims have been amended to remove the trade name and to include the scientific names according to IUPAC regulations. For the examiner's information, attached as Exhibit 1 is a list which identifies the specific scientific names for the trade named material in the claims and no new matter is included by this amendment. For the sake of clarity, with reference to the prior art on page 3, the particular scientific names for Eudragit L and Eudragit S have been added to the specification. As this information was in the prior art, no new matter is included by the substitution of the scientific names for the trade names.

Claims 1 through 6, 8, 15 and 19 were rejected under 36 U.S.C. Section 102(e) as being anticipated by Watts U.S. Patent No. 6,228,396. To have anticipation, each and every element of the claim must be found in a single prior art reference. In re Bond 910 F. 2d 831, (Fed. Cir. 1990). "Even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. In re Donohue 766 F. 2d 531, 533 (Fed. Cir 1985).

Watts does not anticipate the applicant's invention. As the examiner admits, Watts discloses a colonic drug delivery to the colonic region, using a starch capsule containing the drug, the starch capsule provided with a coating such that the dissolution of the capsule depends on dissolution of the coating. The coating is chosen for dissolution to occur predominately in the colon. Col. 2, l. 4-28. (See also Fig. 3 which is a comparison of the uncoated capsule versus the coated capsule).

The applicant's invention on the other hand utilizes different polymers or mixtures of polymers in combination with portions of the active ingredient itself, such that the active ingredient is mixed with and integral with the selected polymers or mixture of polymers and then these are combined together so as to release portions of the active ingredient in different portions of the stomach depending upon the pH which ranges from 6 to 7. This provides a multiphasic release of the active ingredient as the active ingredient portions are released from their specific polymers of mix or polymers during passage through the stomach.

For example, as described on page 5, l. 22-24, capsules can contain granules or pellets of three types, such as granules having coatings including polymers or mixtures of polymers soluble starting from a pH of 6 to a pH of 7. In example 2, these are a pH of 6, 6.5 and 7, mixed in an equal ratio of 1:1:1 in a quantity corresponding to 400 mg of mesalazine in each capsule. The results in use are shown in Table 19, showing an even drug delivery over time.

No such system is shown in Watts, and as each and every element of the claim is not found in Watts, claims 21, 2-6, 8, 15, 16, 18 and 19 are not anticipated by Watts.

Claims 1-3, 5, 6, 8, 15, 16, 18 and 19 rejected as being anticipated by Yajima, et al U.S. Patent No. 5,972,373. Again, the applicant's invention is not anticipated by the cited patent. Yajima is directed to the use of high polymers to mask unpleasantly tasting drugs. Monoglycerides are used as the masking polymer because they are soluble in the stomach. While the integration of the unpleasant tasting drug with a monoglyceride is disclosed, there

is no consideration for a multiphasic release by combining portions of an active ingredient with different polymers or mixtures of polymers which dissolve at different pH's so as to achieve drug delivery in different portions of the stomach. Consequently, as each and every element of the claim is not found in Yajima, et al, the cited claims are not anticipated thereby.

Claims 1-16 and 19-20 were rejected as being unpatentable for obviousness over Watts in view of Ishizuka, et al U.S. Patent No. 6160017 or Ishizuka in view of Watts.

As discussed above, Watts concerns the coating of a starch capsule and does not teach or suggest the integration of different polymers or mixtures of polymers which dissolve at different pH values with portions of a dosage of an active ingredient, and then the combination of these into a formulation for multiphasic delivery.

Ishizuka, et al describes a composition for the treatment of inflammatory bowel disease, namely conagenin. While Ishizuka apparently discloses a new treatment agent, the description in the patent concerning the delivery is not limited to any particular combination and in fact Ishizuka states "no particular limitation is imposed on the preparation form the agent for preventing and treating ulcerous colitis and or Cron's disease according to the present invention and the form may be suitably determined according to the purpose thereof". The patent then goes on to describe the various conventional forms for delivery. It is particularly notable that none of these describes the particular use of different polymers or mixtures of polymers which release at different ph's which are combined with portions of an active ingredient so as to cause multiphasic release during passage through the stomach. In particular, with reference to table 19 of the present application, it is seen that the use of the inventive formulation utilizing a combination of three portions, combined with polymers or mixture of polymers soluble at different pH's when integrated together provide more homogenous tissue concentrations of mesalazine than those of the prior art formulations which enables the active ingredient to perform it's activity in all anatomical areas of the